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PATENTS

MAILING CERTIFICATION

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[Signature]
Bruce S. Londa

#8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty's Docket No: 101195-65

Examiner : TBA

Group Art Unit TBA

Applicant : Stefan Anker, et al.

Appln. No. : 10/019,452

Filed : February 25, 2002

For : Therapy and Use of Compounds in Therapy

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INFORMATION DISCLOSURE STATEMENT

Hon. Assistant Commissioner of Patents
Washington, D.C. 20231

Dear Sir:

The following sections are being submitted for this Information

Disclosure Statement:

- Sec. 1 - Preliminary Statements
- Sec. 2 - Identification of Time of Filing
- Sec. 4 - Statements with Respect to Listing of Information
- Sec. 5 - Statements with Respect to Translations of Non-English Information
- Sec. 6 - Statements with Respect to Copies of Listed Information Items Accompanying This Statement
- Sec. 8 - Concise Explanation of Listed Information Items

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Section 1
Preliminary Statements

Applicants submit herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56.

While this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56 it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(b) the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

Section 2
Identification of Time of Filing

This Information Disclosure Statement is filed before the issuance of the first office action.

The art was cited in the specification of the present application.

Section 4
Statements with Respect to Listing of Information

A list of the patent(s) and/or publications is set forth on the attached pages of Form PTO-1449 (modified).

a) U.S. patent no. 5,858,998 in the English language is believed to be the equivalent of German patent 197 17 252.

Section 5
Statements with Respect to Translations of
Non-English Information

No English language translations of the foreign language patents, publications or information or parts thereof are readily available.

Section 6
Statements with Respect to Copies of Listed Information
Items Accompanying This Statement

A copy of each of the items on PTO-1449 (modified) is supplied herewith.

Section 8
Concise Explanation of Listed Information Items

A concise explanation of the items listed on PTO-1449 (modified) is given for each listed item.

German 297 17 252

U.S. patent no. 5,858,998 is believed to be an equivalent of this German patent. A copy of the U.S. patent is attached to the German patent.

PCT/EP95/04533

The invention concerns a process for preparing isoursodesoxycholic acid, wherein the ursodesoxycholic acid is first esterified and the resultant ursodesoxycholic acid ester is reacted by the Mitsunobu reaction to form isoursodesoxycholic acid ester. The isoursodesoxycholic acid ester is then saponified to form

isoursodesoxycholic acid. The process is distinguished by the simplicity with which it is carried out and the high yields and amounts in which the isorusodesoxycholic acid is obtained.

PCT/EP97/04325

A new use is disclosed of 3 α -7 β -dihydroxy-5 β -cholic-24 acid (ursodeoxycholic acid, UDCA) or its derivatives to improve the immune system of HIV-infected patients, as well as in particular for preventing and treating HIV infections.

Publication (AK on page 2 of 1449)

This publication is discussed on page 3 of the present application. "Originally, UDCA was registered for the medical treatment of gallstones." ... "In analogy, UDCA is used in other cholestatic disorders like primary sclerosing cholangitis." ... "Regarding its mode of action, most authorities regard increased bile flow and a reduced hepatocellular insult as a result of improved bile flow and altered bile salt patterns as the main modes of UDCA action in chronic cholestatic liver diseases."

Respectfully Submitted,



Bruce S. Londa (33,531)
Attorney for Applicant
Norris, McLaughlin & Marcus P.A.
220 East 42nd Street, 30th Floor
New York, N.Y. 10017
Telephone: 212-808-0700
Facsimile: 212-808-0844

LIST OF PATENTS AND PUBLICATIONS				Attorney Docket: 101195-65		Serial No. 10/019, RECEIVED	
APPLICANT'S INFORMATION				Applicant: Stefan Anker et al.		Filing Date: JUL 26 2002	
DISCLOSURE STATEMENT (Form PTO-1449 Modified)				Filing Date: February 25, 2002		Group: TBA	
U.S. PATENT DOCUMENTS							
Examiner's Initial	Document Number	Date	Name	Class	Sub Class	Filing Date	If appropriate
AA							
AB							
AC							
AD							
AE							
AF							
AG							
AH							
AI							
AJ							
AK							
FOREIGN PATENT DOCUMENTS							
	Document Number	Date	Country	Class	Sub Class	Translation	Yes No
AL	297 17 252	4/1998	Germany				✓
AM	PCT/EP95/04533	6/1996	PCT				✓
AN	PCT/EP97/04325	2/1998	PCT				✓
AO							
AP							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
AR	U. Leuschner, et al.; "Our 10 Year Experience in Gallstone Dissolution Comparison with the National cooperative Gallstone Study (HCGS, USA) and the Tokyo Cooperative Gallstone Study (TCGS, Japan)" Gastroenterology 1982, 82:1113						
AS	K. Lindor et al.; "Effects of Ursodeoxycholic Acid on Survival in Patients with Primary Biliary Cirrhosis" Gastroenterology 1996; 110; pgs.1515-1518						
AT	U. Beuers, et al.; "Therapie der autoimmunem Hepatitis, primär biliären Zirrhose und primär sklerosierenden Cholangitis Konsensus der Deutschen Gesellschaft für Verdauungs- und Stoffwechselkrankheiten" Z. Gastroenterol 1997; 35; pgs. 1041-1049						
EXAMINER:				DATE CONSIDERED: AUG 08 2002			
<p>• EXAMINER: Initial if Reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformation and not considered, include copy of this form with next communication to applicant.</p>							

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LIST OF PATENTS AND PUBLICATIONS APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Form PTO-1449 Modified) JUL 2 2 2002		Attorney Docket: 101195-65	Serial No. 10/019,452	RECEIVED JUL 26 2002		
Applicant: Stefan Anker et al.		Filing Date: February 25, 2002				
Group: TBA		TECH CENTER 1600/2900				
U.S. PATENT DOCUMENTS						
Examiner's Initial	Document Number	Date	Name	Class	Sub Class	Filing Date If appropriate
AA						
AB						
AC						
AD						
AE						
FOREIGN PATENT DOCUMENTS						
	Document Number	Date	Country	Class	Sub Class	Translation
AF						
AG						
AH						
AI						
AJ						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)						
AK	J. Palma et al.; "Ursodeoxycholic Acid in the Treatment of Cholestasis of Pregnancy: a Randomized, Double-blind Study Controlled with Placebo" Journal of Hepatology 1997; 27; pgs. 1022-1028					
AL	J. Goulis, et al.; "Randomised Controlled Trials of Ursodeoxycholic-acid Therapy for Primary Biliary Cirrhosis: a Meta-analysis" The Lancet, Vol. 354, September 25, 1999; pgs. 1053-1060					
AM	M. Trauner et al.; "Review Article: Mechanisms of Action and Therapeutic Applications of Ursodeoxycholic Acid in Chronic Liver Diseases" Aliment Pharmacol Ther. 1999; 13; pgs. 979-995					
AN	M. Plauth; et al.; "ESPEN Guidelines for Nutrition in Liver Disease and Transplantation"; Clinical Nutrition 1997; 16; pgs. 43-55					
AO	O. Selberg, et al.; "Identification of High-and Low-Risk Patients Before Liver Transplantation: A Prospective Cohort Study of Nutritional and Metabolic Parameters in 150 Patients" Hepatology 1997; 25; pgs. 652-657					
AP	J. Greve, et al.; "Bile Acids Inhibit Endotoxin-induced Release of Tumor Necrosis Factor by Monocytes: an <i>In Vitro</i> Study" Hepatology 1989; 10(4) pgs. 454-458					
AQ	Y. Hori et al.; "Protective Effect of the Intravenous Administration of Ursodeoxycholic Acid Against Endotoxemia in Rats with Obstructive Jaundice" Surg Today, 1997; 27; pgs 140-144					
AR	C. Lu et al.; "Efficacy of Ursodeoxycholic Acid in the Treatment of Patients with Chronic Hepatitis C" Journal of Gastroenterology and Hepatology 1995;10; pgs. 432-437					
AS	A. Anker et al.; "Elevated Soluble CD 14 Receptors and Altered Cytokines in Chronic Hepatitis B"; Am. J Cardiol 1997; 79; pgs. 1426-1430					
EXAMINER:				DATE CONSIDERED:		
• EXAMINER: Initial if Reference considered, whether or not citation is in conformance with MPEP 2009, Drawings through citation if not in conformation and not considered, include copy of this form with next communication to Applicant.						